Cost-effectiveness of test strips for blood glucose monitoring

CARLOS MARTÍN-SABORIDO[1], CRISTINA ANTÓN-RODRÍGUEZ[1], DIANA MONGE-MARTÍN[1]

[1]Health Technology Assessment Unit, Faculty of Health Sciences, Universidad Francisco de Vitoria

Abstract

Objectives: The present study aims to develop an economic evaluation to compare individually and vial-packaged strips for glucose monitoring to show if the aforementioned concerns could be overcome in an efficient way using individually package strips.

Methods: An economic evaluation using a mathematic model was developed to compare the costs and effects of using individual vs. vial-packaged strips (IP vs. VP) including three different settings which represents the pathway of a diabetic patient: home, hospital and primary care.

Three different scenarios were modelled where different rates of hypoglycemic events, waste of strips and nosocomial infections were used.

Uncertainty was tested using one-way and probabilistic sensitivity analysis.

Results: Globally, IP strips saved money and got more QALYs (9.4 €, 0.0005 per patient) , which conferred a dominant position to individual packaged strips with no reduction in nosocomial events, and 25% less hypoglycemic events and 26% reduction in the use of strips. We found that the Home module accounted for more QALYs than PC and Hospitalization although the difference was small. This differences remained in the three scenarios and through the sensitivity analysis.

Conclusions: Under the assumption of wrong measurements due to bad storage and manipulation, the use of individual packaged strips could avoid 12%-43% of hypoglycemic events and save 4%-8% of total costs.

Key words: glucose monitoring, glucometer, cost-effectiveness, environment contaminants, hypoglycaemia.

INTRODUCTION

Blood glucose monitoring is a keystone part of diabetes care. For many patients with diabetes, daily self-injection of insulin and self-monitoring of blood glucose (BG) allow diabetes patients to determine their BG level and to use the information as part of their treatment program.

Ginsberg et al.[1] describe that the overall performance of BG meters is a combination of the analytical performance of the instrument, proficiency of the patient, and quality of the test strips and the underlying measurement technology, stating that the inaccuracy of blood glucose monitoring (BGM) systems could come from four main sources: strip factors (as with any manufactured product, there is a small amount of strip-to-strip variation, which will therefore lead to some inaccuracy in blood glucose readings), the electrochemical technology involves a biosensor employing enzyme mechanisms (e.g. glucose oxidase and its biochemical reaction, generating a charge that is measured and translated as a blood glucose concentration on the meter display screen)[2] physical factors (the most common influencers are altitude and temperature) patient factors (patient technique, hand washing) and pharmacological factors (e.g. acetaminophen, L-dopa, tolazamide, and ascorbic acid interacting with the electrode).

The importance of measurements accuracy is evidenced in the International Organization for Standardization (ISO) standard 15197 for BGM systems[3] but despite these standards for the glucose systems based on strips, there are performance differences among available glucometers.

Corresponding author

Carlos Martin Saborido.
Unidad de Evaluación de Tecnologías Sanitarias.
Universidad Francisco de Vitoria.
Carretera Pozuelo-Majadahonda Km 1.800
28223 Pozuelo de Alarcón. Madrid. Spain.
Telephone: (+34) 91.351.03.03.
Fax: (+34) 91.351.17.16.
c.martin@ufv.es

However, two main concerns have arisen lately about the wrong manipulation and wrong storage of strips: bacterial contamination[4,5], underestimation of blood glucose levels[6,7]. This later concern was highlighted after a warning note was delivered by the Spanish Drug and Devices Agency (AEMPS) preventing of abnormally high values using blood glucose strips packaged in vials[8]. This note stressed on the correct manipulation and storage of vials including the importance of keeping the expiration date of the strips.

In this regard, this study pretends to evaluate the efficiency (cost-effectiveness) of using individually packaged strips versus vial packaged strips in a model including three different settings which represents the pathway of a diabetic patient: home, hospital and primary care.

SUBJECTS AND METHODS

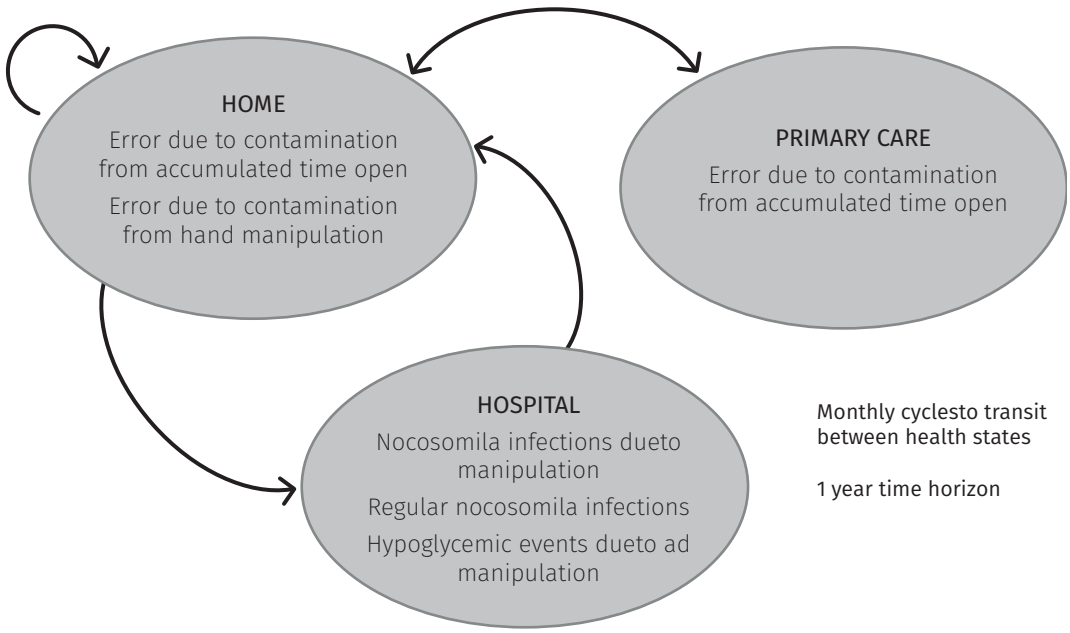
Study design

We have developed a mathematical model to estimate the cost-effectiveness of using individual packed strips (IP) vs vial packaged strips (VP). This model evaluated the costs and effects of each strategy (IP, VP) in terms of hypoglycemic events, nosocomial infections and use of strips. That is, each of the hypoglycemic events and nosocomial infections produce a decrease in the quality of life of patients as well as costs associated to the treatment of those events. On the other hand, the use of strips is recorded in order to account for the waste of strips due to duplicate measures in case of an irregular read.

The model is based on Markov transitions, that is, a cohort of patient transit within a set of health states with a probability (transition probability) defined using data from different sources. In this model, we have defined three modules interconnected (Figure 1). This simulated cohort of patients has a mean age of 55 years with a sex distribution of 50% women, because the aim of the economic evaluation between strategies, it is not relevant to simulate any special cohort of patients.

FIGURE 1

CONCEPTUAL SCHEME OF THE MODEL WITH TRANSITIONS



Fuente: Prepared by the authors.

The patients remain in the Home module until they have to visit the GP (because a regular visit or because a problem non-related with the control of the diabetes but with the use of a blood test strip) or have a problem which need hospitalization. In any of the cases, after the PC visit or the Hospitalization the patient will come back to the home module. Either the GP visit or the hospitalization occurs in one cycle.

In the three modules, the risk of hypoglycaemic events (within the three modules), use/waste of strips and infections (only at the hospital) are the outcomes of interest along with the costs and QALYs derived from the aforementioned outcomes.

Apart from the base case scenario, two scenarios have been identified within each module: scenario 1 low rate of hypoglycemic events and low rate of infections (nosocomial), base case medium rates, scenario 2 high rates. Scenarios can be selected independently for each module (Table 1).

Either the base case or the scenarios, are based on several assumptions based on conversations between the authors and several experts given the scarcity of data about use of strips. These assumptions are described below.

Data sources and assumptions

Data used to populate the model have been collected from published papers, when a data where required and was not available in any paper, we decided to calculate ourselves from primary data and consult with experts. After this exercise, we made an assumption for the case at hand. Table 2 describes all data used to define parameters for the model alongside with their sources.

- Assumptions in the Home module:
  Vials at home could be contaminated because accumulated time opened and therefore produce wrong estimates of glycemia e.g. glucose oxidase-based meter commonly affected by a wide variety of common medications (such as Acetaminophen, ascorbic acid among others), while interfering with the accuracy of blood glucose readings (25% error) as well as the time of the enzyme in contact with the air due to the opened time of vials[2]. This could lead to wrong insulin doses and therefore hypoglycemic events. The manipulation of strips without hand washing would produce contamination of the strips in the vial and again wrong estimates,

TABLE 1

BASE CASE AND SCENARIO DESCRIPTION

	Home	Primary Care	Hospitalization
Base case	Base case (IP: HE reduction of 20% from VP; wastage reduction 20% of wastage from VP)	Base case (IP: HE reduction of 20% from VP; wastage reduction 20% of wastage from VP)	Base case (IP: HE reduction of 20% from VP; reduction in Nosocomial I of 20% from VP)
Scenario 1	Low rate of hypoglycemic events (reduction of 10% from VP) and low rate of wastage (reduction 10% of wastage from VP)	Low rate of hypoglycemic events (reduction of 10% from VP) and low rate of wastage (reduction 10% of wastage from VP)	Low rate of hypoglycemic events (reduction of 10% from VP) and reduction in Nosocomial I of 10% from VP)
Scenario 2	High rate of hypoglycemic events (IP reduction of 30% from VP) and same rate of wastage as base case (IP reduction 20% of wastage from VP)	High rate of hypoglycemic events (IP reduction of 30% from VP) and same rate of wastage as base case (IP reduction 20% of wastage from VP)	How rate of hypoglycemic events (IP reduction of 30% from VP) and reduction in Nosocomial Infection of 30% from VP)

IP, individually packaged strips; **HE**, hypoglycemic events; **DM1**, Diabetes type 1; **DM2**, Diabetes type 2; **VP**, vial packaged

Fuente: Prepared by the authors.

TABLE 2

PARAMETERS USED IN THE MODEL WITH SOURCES PER MODULE

		Parameter value	Source
Home	Vial of strips		
	Rate of contamination of the vial	0.450	Perez-Ayala et al.[4]
	Proportion of wasted strips Vials	0.128	Isla-Pera et al.[11]
	Individually packaged strips		
	Proportion of hypoglycaemic event reduction IP	0.200	Assumption
	Rate of contamination of the IP	0.070	Perez-Ayala et al.[4]
	Proportion of wasted strips reduction IP	0.200	NG et al.[12]
	Costs		
	Cost per stay	€ 4,169.440	Public Prices C. Madrid[13]
	Cost of nosocomial infection	€14,325.757	Ministry of Health[14]
	Cost per hypoglycaemic event	€ 3,660.62	Crespo et al.[15]
	Cost per strip	€ 0.300	Assumption
Primary care	Vial of strips		
	Rate of contamination of the vial	0.450	Perez-Ayala et al.[4]
	Proportion of wasted strips Vials	0.128	Isla-Pera et al.[11]
	Individually packaged strips		
	Proportion of hypoglycaemic event reduction IP	0.200	Assumption
	Rate of contamination of the IP	0.070	Perez-Ayala et al.[4]
	Proportion of wasted strips reduction IP	0.200	Assumption
	Costs		
	Cost per stay	€ 4,169.440	Public Prices C. Madrid[13]
	Cost of nosocomial infection	€ 14,325.757	Ministry of Health[14]
	Cost per hypoglycaemic event	€ 1,827.220	Crespo et al.[15]
	Cost per strip	€ 0.300	Assumption
Hospitalization	Vial of strips		
	Probability nosocomial infection	0.056	EPINE-EPPS 2014[16]
	Probability of hypoglycaemic event IP hospital	0.660	Based on fitted curve
	Rate of contamination of the vial	0.450	Perez-Ayala et al.[4]
	Proportion of wasted strips Vials	0.100	Assumption
	Individually packaged strips		
	RRR for contamination	0.800	Assumption
	Probability of hypoglycaemic event IP hospital	0.524	Based on fitted curve
	Rate of contamination of the IP	0.070	Perez-Ayala et al.[4]
	Proportion of wasted strips IP Hospital	0.040	NG et al.[17]
	Costs		
	Cost per stay	€ 4,169.440	Public Prices C. Madrid[13]
	Cost of nosocomial infection	€ 14,325.757	Ministry of Health[14]
	Cost per hypoglycaemic event	€ 1,827.220	Crespo et al.[15]
	Cost per strip	€ 0.300	Assumption
	Hospital stay in days (diabetes admission)	11.680	Dominguez et al.[18]
	Hospital stay in days because of a nosocomial infection	19.856	EPINE-EPPS 2014[16]
	Mortality rate because nosocomial infection	0.010	EPINE-EPPS 2014[16]
	Rate of admitted population increasing days of stay	0.025	EPINE-EPPS 2014[16]
	# strips per patient	3.400	Nichols et al.[19]
	Nurse visits (average/year)	4.800	Mata-Cases et al.[20]
Hypoglycemic events	Probability severe HE in DM1	0.0003	Orozco-Beltran et al.[21] Used for Home and PC
	Probability severe HE in DM2	0.0002	Orozco-Beltran et al.[21] Used for Home and PC
	Probability non-severe HE in DM1	0.029	Orozco-Beltran et al.[21] Used for Home and PC
	Probability non-severe HE in DM2	0.026	Orozco-Beltran et al.[21] Used for Home and PC
Utility	Disutility DM2 Severe HE	-0.078	Harris et al.[22]
	Disutility DM1 Severe HE	-0.047	Harris et al.[22]
	Disutility DM2 non-severe HE	-0.005	Harris et al.[22]
	Disutility DM1 non-severe HE	-0.004	Harris et al.[22]
	Utility DM1	0.831	Harris et al.[22]
	Utility DM2	0.863	Harris et al.[22]
	Utility admitted hospital	0.855	Harris et al.[22]
	Disutility hypoglycaemia Hospital	-0.070	Harris et al.[22]
	Disutility nosocomial infection	-0.140	Assumption as double of disutility of hypoglycaemia

Fuente: Prepared by the authors.

wrong calculation of doses and hypoglycemic events along with the wastage of strips. Using individual packaged strips could avert those events derived from contamination of the strips in the vial. This situation is modelled here.

- Assumptions in the PC module:
  At the nursing office in primary care, there are usually 2-3 opened vials without the date written as should when is recommended by the manufacturer. The risk is to have unreliable measures leading to wrong results and hypoglycemias. The base line assume one of the vials is opened more than 90 days so part of the strips will give small errors leading to hypoglycemias associated with high doses of insulin and will give big errors leading to dispose strips and increasing the wastage. Base case: half vial of 50 strips disposed of because wrong measures, that is 25 strips disposed from 50 available. This assumption was tested in a univariate sensitivity analysis and was analysed separately due to the level of uncertainty.

- Assumptions in the Hospitalization module
  Vials at the hospital can be contaminated by the manipulation of nurses using gloves without changing between patients, in a way that some germs can be transmitted from patient to patient through the gloves and can lead to nosocomial infections. On the other hand, because the vials usually remains open between patient sampling, vials accumulate time opened and errors due to environment exposure can lead to hypoglycemic events. The base case assumes half vial of 50 strips disposed of because wrong measures, that is 25 strips disposed from 50 available.

- Data analysis
  The model was developed using Excel® and all analysis were made within this software. The currency used was €. All costs were updated to 2014 using an inflation rate of 3%[9]. The perspective of the evaluation is the National Health Service so no indirect costs have been included. The time horizon is 1 year divided in 12 monthly cycles as is the relevant time span to identify relevant costs and benefits from the strategies. The results of the model were expressed in number of hypoglycemic events, nosocomial infections, strips used/wasted, costs related to every event, total costs and QALYs. The global result of the model was expressed in cost per QALY for each option and using the incremental cost-effectiveness ratio (ICER) which showed the differences in costs divided by the differences in QALYS of each option (IP vs. VP).

Due to the uncertainty around the parameters, two sensitivity analysis have been planned: one-way sensitivity analysis (OWSA) and a probabilistic sensitivity analysis (PSA). The OWSA consist of simply varying one value in the model by a given amount (SD, CI or a percentage if none of the former are available), and examine the impact on the model's results. The PSA is done using a random value from probabilistic distribution of each of the values used in the model instead of the deterministic value, this process is repeated 1000 times and the average is used as the PSA result. For the PSA, we have used the probabilistic functions recommended in the literature[10].

RESULTS

Base case results

The results of the model set a dominance situation for IP option with less costs and more QALYs than VP option. This produced a negative ICER.

A shows the results of the base case analysis where the number of hypoglycemic events is lower for IP option in all modules as well as infections in hospitalization module. When all modules are added, total costs in the VP option are higher than IP option (€233,891.99 vs. €220,576.52) and QALYs are higher for IP option (10,256.35 vs. 10,255.70). This trend is kept for the two scenarios.

Although differences in the use and waste of strips is also in favour of IP option, this is not a key cost driver as the cost per strip is quite low (€ 0.3).

Globally, IP option result in 25% less hypoglycemic events, 29% less wasted strips, 7 % less

costs and 1% more QALYs. These results confer a dominant position (less costs and more QALYs) to IP versus VP option.

When we examined each module, we found that the differences in costs between options are quite similar between Home, PC and Hospitalization (€4,227.14, €4,155.26 and €4,932.88 respectively) whereas Home module account for more QALYs than PC and Hospitalization although the difference is small (0.36, 0.14 and 0.15 QALYs respectively).

In the hospitalization module, the key driver for costs are those related to the admittance resulting in 71% in IP option and 66% in VP option, then the number of hypoglycemic events, responsible of 20% for the module costs in VP option and 17% in IP option followed by nosocomial infection with 14% for VP and 12% for IP Costs of strips contribute with less than 1%. Once admittance costs are eliminated, hypoglycemic events are responsible of 60% of total costs and nosocomial infections of 40%.

Distribution of costs in the Home module are quite different to the Hospitalization module with a 96% and 97% of total costs imputable to the cost of strips in IP and VP options respectively.

Finally, in PC module the costs of hypoglycemic events accounts for 28% of total costs and the cost of strips for the remaining 72% in VP option, while in IP option the contribution of both components is quite similar, 49% and 51%.

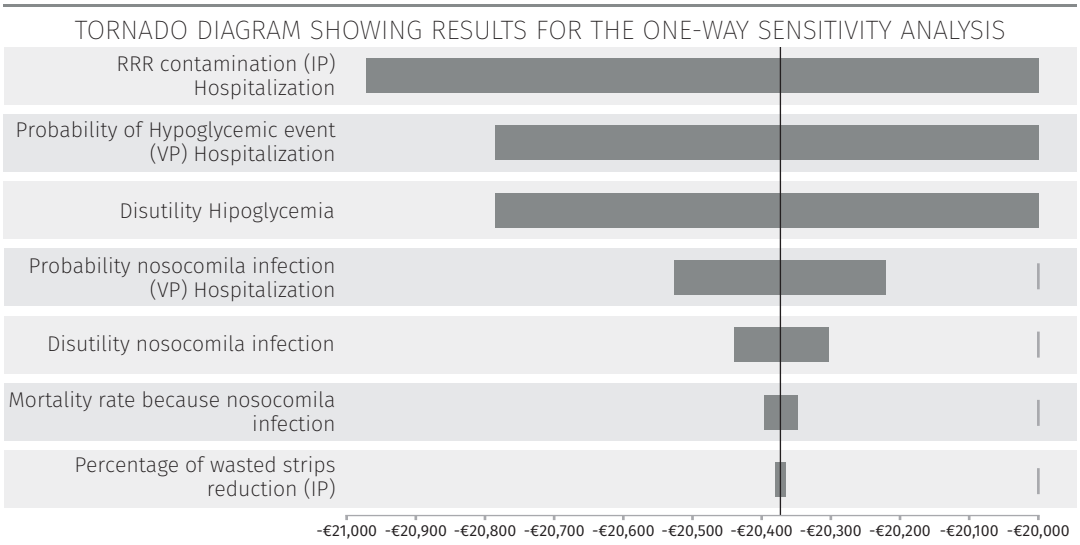
In terms of QALYs, the key drivers are hypoglycemic events and nosocomial infections as both are the parameters responsible of deduct utility. In this context, only hospitalization module shows QALYs for these two parameters with hypoglycemic events leading the sharing with an 85% of total QALYs.

When scenarios are analysed (B and C) we found similar results, VP option gets higher costs and lower QALYs. Same situation is found in both scenarios in relation to the module examination, key drivers for costs and QALYs remain analogous to the base case.

Sensitivity analysis

The OWSA was done using a range of values for every parameter based on its SD, CI or a reasonable range of values. Tornado diagram in Figure 2 has a vertical line setting the base case ICER (cost per QALY) and each of the horizontal lines shows the change in this ICER when the parameter value is modified, thus, the ends of the horizontal

FIGURE 2



RR: reduction of relative risk.

Fuente: Prepared by the authors.

bars are the ICER for the minimum and maximum values of the range used.

In this case none of the values achieves remarkable changes. As can be seen, the ICER is a negative value due to the dominance situation of IP over VP (IP less costly and more effective than VP).

An independent univariate sensitivity analysis was done for the number of wasted strips assumed in PC due to the uncertainty of the assumption. Figure 3 shows that a small change in the ICER is observed but keeping the dominance of IP over VP, this dominance is reflected in the fact that the correspondent value of the ICER for each value of wasted strips (5, 10, 15, 20, 25) remains below zero, that is keeping negative figures and therefore the dominance.

PSA results were quite similar to the base case with only minor changes in some values due to the probabilistic aspect of this analysis (Table 4). One of these differences are those related to the QALYs, in the base case and scenario 2 the total account of QALYs is in favour of IP option while in scenario 1 this is in favour of VP. This reflects the uncertainty around the utility parameters as the QALY is the result of multiply utility by the events (hypoglycemic and nosocomial infections) and as can be seen in Table 4, the number of events remains similar to the figures in the deterministic analysis (Table 3).

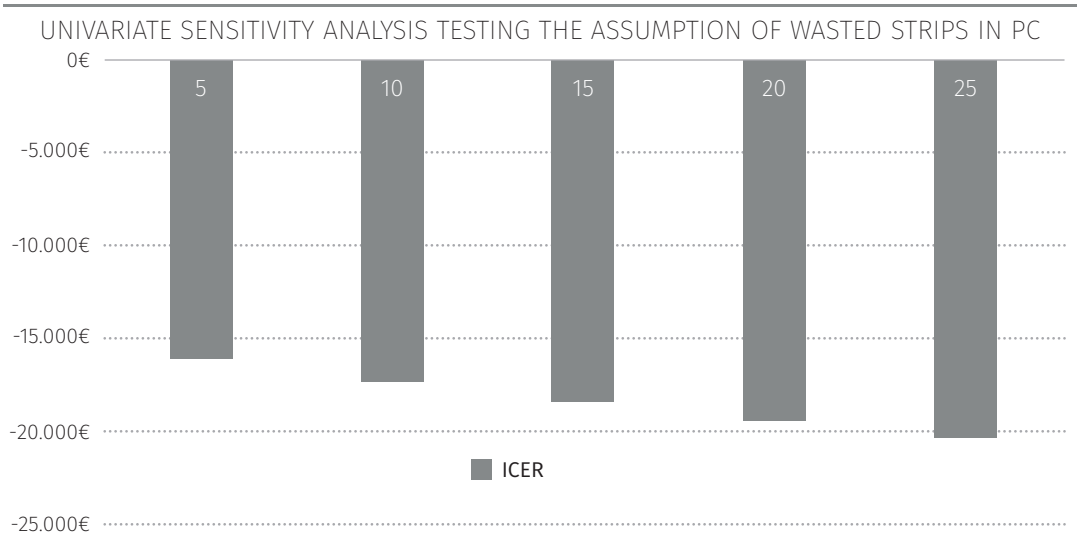
DISCUSSION

After the publication of some data about how the incorrect manipulation of strips could induce to wrong measures and undesirable effects[4], it is necessary to quantify these events and figure out the costs and effects of changing vial packaged strips (VP) by individual packaged strips (IP).

The present study has used a model to explain the consequences of this change using published data and a number of assumptions based on opinions when there were lack of evidences. The results showed that when IP are used the unwanted events decrease as well as the global costs despite of the same cost per strip for VP and IP.

The key drivers for costs explored in the results section changed between options because of the higher number of HE in VP for the three modules vs IP where the main driver is the cost of strips because a low rate of HE.

FIGURE 3



OWSA: One-way sensitivity analysis (supplemental material); **PC**: primary care

Fuente: Prepared by the authors.

TABLE 3

DETERMINISTIC RESULTS: A. BASE CASE RESULTS B. SCENARIO 1 C. SCENARIO 2

			Infections	Hypoglycaemic events	Use of strips	Waste of strips	Total Costs (€)	Total QALYs
A	Home	IP	-	256.822	407,248.231	41,769.049	139,083.488	10,245.574
		VP	-	321.027	407,248.231	52,211.312	143,310.742	10,245.220
	PC	IP	-	102.729	5,429.976	556.921	3,547.391	-0.567
		VP	-	128.411	16,289.929	2,088.452	7,702.666	-0.708
	Hospitalization	IP	0.626	7.315	47.462	1.898	77,945.637	11.341
		VP	0.783	9.143	47.462	4.746	82,878.586	11.190
B	Home	IP	-	288.924	407,246.913	46,990.028	141,196.658	10,245.364
		VP	-	321.026	407,246.767	52,211.124	143,310.227	10,245.183
	PC	IP	-	115.569	5,429.959	626.534	3,787.178	-0.638
		VP	-	128.410	16,289.871	2,088.445	7,702.639	-0.708
	Hospitalization	IP	0.705	8.229	47.461	1.898	80,411.424	11.266
		VP	0.783	9.143	47.461	4.746	82,878.288	11.190
C	Home	IP	-	224.719	407,247.206	41,768.944	138,535.851	10,245.726
		VP	-	321.026	407,246.767	52,211.124	143,310.227	10,245.183
	PC	IP	-	89.887	5,429.963	556.919	3,328.467	-0.496
		VP	-	128.410	16,289.871	2,088.445	7,702.639	-0.708
	Hospitalization	IP	0.548	6.400	47.461	1.898	75,479.400	11.416
		VP	0.783	9.143	47.461	4.746	82,878.288	11.190

Fuente: Prepared by the authors.

TABLE 4

PSA RESULTS: A. BASE CASE RESULTS B. SCENARIO 1 C. SCENARIO 2

			Infections	Hypoglycaemic events	Use of strips	Waste of strips	Total Costs (€)	Total QALYs
A	Home	IP	-	253.997	407,248.231	41,536.282	139,584.794	10,046.273
		VP	-	322.400	407,248.231	52,211.312	143,743.805	10,045.056
	PC	IP	-	102.238	5,463.282	557.943	3,549.567	-0.587
		VP	-	134.497	17,027.484	2,183.011	8,024.255	-0.781
	Hospitalization	IP	0.640	7.216	47.062	1.867	78,037.893	12.451
		VP	0.796	8.979	47.240	4.935	82,629.156	12.600
B	Home	IP	-	258.537	407,248.231	46,990.028	141,873.742	9,998.054
		VP	-	322.289	407,248.231	52,211.124	143,728.306	10,070.704
	PC	IP	-	101.111	5,339.715	626.534	3,498.826	-0.588
		VP	-	130.213	16,483.390	2,088.445	7,804.972	-0.755
	Hospitalization	IP	0.655	8.395	47.756	1.898	80,142.208	12.483
		VP	0.730	9.275	47.308	4.746	81,922.064	12.625
C	Home	IP	-	260.495	407,248.231	41,502.947	139,047.998	10,059.325
		VP	-	321.164	407,248.231	52,211.312	143,217.893	10,052.471
	PC	IP	-	103.840	5,413.779	561.267	3,594.921	-0.597
		VP	-	121.648	15,384.487	1,972.370	7,291.345	-0.719
	Hospitalization	IP	0.542	6.425	47.301	1.987	75,476.793	12.390
		VP	0.814	9.035	47.702	4.690	82,921.014	12.599

Fuente: Prepared by the authors.

In terms of effectiveness, QALYs are so similar in both options because this parameter is fed with the utility and disutility of HE events and the severe ones had a very low probability to occur (0.0003 monthly). Also the nosocomial infections would reduce the QALYs in the VP option but again the probability is low (0.056) and the percentage of people with diabetes admitted at the hospital is 0.002 for DM1 and 0.0007 for DM2.

When the sensitivity analysis is used to test the uncertainty, results are quite similar except for total QALYs in scenario 1 where the PSA provides more QALYs for VP option although the number of events remained similar to the deterministic analysis. The explanation of this fact is again the uncertainty around the utility values moreover when the rates of events are closer as happens in scenario 1. In any case differences in the number of events and in costs highlight the value for money of IP strategy.

The interpretation of this results lead us to think that a change is needed in the way the strips are used to improve the efficiency of the blood glucose testing. This interpretation should be taken with caution if speak in absolute numbers but the wrong manipulation of strips clearly incurred in serious HE which can be avoided along with the related costs, moreover when one alert about the manipulation of strips has led to a wrong glucose reading.[8]

The mean limitation of this study relies on the lack of clinical data related to the findings about contamination of strips in hospital settings[4] and to the use of vials at home and PC what lead us to make a few assumptions supported by consultation with experts. This assumptions really seem to overestimate the wastage of strips and wrong estimates of glycemia conferring to the study a conservative perspective. It can be argued that individually packaged strips could have pinholes and cause a major recall. This latter issue along with strong data collection should be addressed in further economic evaluations to improve the accuracy of the results. Lastly, it is noteworthy that there are meaningful differences in accuracies and bias between strip bands but we lack of this information so further studies should address this point

Some of the limitations have been addressed with a number of sensitivity analysis as mentioned above.

Summarizing, the use of individual packaged strips could avoid between 12% (scenario 1) and 43% (scenario 2) of hypoglycemic events and save between 4% (scenario 1) and 8 % (scenario 2) of total costs incurred because a wrong manipulation and bad storage conditions of the vials packaged strips.

As a take home message, new studies should be design to capture the uncertainties identified in this evaluation: use of vial-packaged strips in PC and collection of nosocomial infections related to the use of strips wrongly manipulated. ■

Declaration of interest:

Cristina Antón Rodriguez and Diana Monge Martín are Universidad Francisco de Vitoria staff with no conflict of interest.

Carlos Martín Saborido is Universidad Francisco de Vitoria staff and has received travel expenses for one meeting from Abbott Laboratories S.A

The abstract of this study has been presented as Poster at the 19th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); October 31-Novembver 2nd 2016, Vienna, Austria.

Funding:

This study has been funded with a grant from Abbott laboratories S.A to the Universidad Francisco de Vitoria.

Author contributions:

Carlos Martín Saborido has design the study, develop the model an participate in the drafting of the manuscript and final approval.

Cristina Antón Rodriguez has participated in the development of the model and drafting of the manuscript and final approval

Diana Monge Martín has participated in the collection of data to populate the model, validation of the model and drafting of the manuscript and final approval.

ABBREVIATIONS

BG	Blood Glucose
CE	Cost-effectiveness
DM1	Diabetes Mellitus Type 1
DM2	Diabetes Mellitus Type 2
ICER	Incremental cost-effectiveness ratio
IP	Individually packaged
NSHE	Non-severe hypoglycemic event
OWSA	One-way sensitivity analysis
PC	Primary Care
PSA	Probabilistic sensitivity analysis
QALY	Quality-adjusted life year
SHE	Severe hypoglycemic event
VP	Vial packaged

REFERENCIAS

1. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol 3(4), 903-913 (2009).
2. Hirsch IB, Bode BW, Childs BP et al. Self-Monitoring of Blood Glucose (SMBG) in insulin- and non-insulin-using adults with diabetes: consensus recommendations for improving SMBG accuracy, utilization, and research. Diabetes technology & therapeutics 10(6), 419-439 (2008).
3. 129 CaC. Sistemas de ensayo para diagnóstico in vitro. Requisitos para los sistemas de monitorización de glucosa en sangre para autodiagnóstico en el manejo de la diabetes mellitus (ISO 15197:2013). (Monograph), (2013).
4. Perez-Ayala M, Oliver P, Rodriguez Cantalejo F. Prevalence of bacterial contamination of glucose test strips in individual single-use packets versus multiple-use vials. J Diabetes Sci Technol 7(4), 854-862 (2013).
5. Verhagen AP, Karels CH, Schellingerhout JM, Willemsen SP, Koes BW, Bierma-Zeinstra SM. Pain severity and catastrophising modify treatment success in neck pain patients in primary care. Manual therapy 15(3), 267-272 (2010).
6. Keffer P, Kampa I. Instability of blood glucose test strips in uncapped vials. 58th Annual Meeting and Scientific Sessions 47(supplement 1), A6 (1998).
7. Sociedad Española De Farmacia H. Nota de prensa del Grupo GPS de la Sociedad Española de Farmacia Hospitalaria, sobre seguridad y coste-eficacia de las tiras reactivas de glucosa en envase individual. 2015(Web Page), (2013).
8. Agencia Española De Medicamentos Y Productos S. Riesgo de obtener una lectura de glucemia erróneamente alta con las tiras reactivas "Glucomen LX Sensor". 2015(Web Page), (2015).
9. López Bastida J OJ, Antoñanzas F., García Altes A., Gisbert R., Mar J. Y Puig- Junoy J. Propuesta de guía para la evaluación económica aplicada a las tecnologías sanitarias. Madrid: Plan Nacional para el SNS del MSC. Servicio de Evaluación del Servicio Canario de la Salud; 2008. Informes de Evaluación de Tecnologías Sanitarias:SESCS Nº 2006/22. 24(2)(154-170), (2008).
10. Briggs A. CK, Sculper M. Decision Modelling for Health Economic Evaluation: Andrew Briggs - Oxford University Press. (2006).
11. Isla Pera P, Castella Lazaro E, Insa Soria R et al. Proporción de carga asistencial generada por la diabetes mellitus en las consultas de enfermería de atención primaria de salud. Endocrinología y Nutrición 62(07), 2-9 (2015).
12. Ng R, Koo S, Johnston R. Multicenter evaluation of bacterial contamination of glucose test strips. In: Clin Chim Acta, Netherlands 1485-1487 (2012).
13. Orden 731/2013, de 6 de septiembre del Consejero de Sanidad, por la que se fijan los precios públicos por la prestación de los servicios y actividades de naturaleza sanitaria de la Red de Centros de la Comunidad de Madrid. (2013).
14. (Msc) MDSYC. Revisión bibliográfica sobre trabajos de costes de la "no seguridad del paciente". Informes, estudios e investigación (NIPO: 35108040X), (2008).
15. Crespo C, Brosa M, Soria-Juan A, Lopez-Alba A, López-Martínez N, Soria B. Costes directos de la diabetes mellitus y de sus complicaciones en Espana˜ (Estudio SECCAID: Spain estimated cost Ciberdem-Cabimer in Diabetes). Avances en diabetología 29 182 (2013).
16. Sociedad Española De Medicina Preventiva SPEHS. Estudio de prevalencia de las infecciones nosocomiales en España: EPINE 1990-2011. (2013).
17. Ng R, Schwartz S, Taylor E. Waste of test strips compared among four blood glucose monitoring systems. Diabetologia 52 S368-S368 (2009).
18. Dominguez-Gonzalez M, Lopez-Pardo M, Ruano-Raviña A, Rey-Liste M, García-Sixto M. Analysis of the management of the process and the variability in the handle of the diabetes mellitus in Galicia. Galicia Clínica 72(3), 9 (2011).
19. Nichols JH. Estimated strip wastage from glucose meter infection control recommendations. Clinica chimica acta; international journal of clinical chemistry 414 91-92 (2012).
20. Mata-Cases M, Roura-Olmeda P, Berengué-Iglesias M et al. Fifteen years of continuous improvement of quality care of type 2 diabetes mellitus in primary care in Catalonia, Spain. International Journal of Clinical Practice 66(3), 289-298 (2012).
21. Orozco-Beltran D, Mezquita-Raya P, Ramirez De Arellano A, Galan M. Self-reported frequency and impact of hypoglycemic events in Spain. Diabetes Ther 5(1), 155-168 (2014).
22. Harris S, Mamdani M, Galbo-Jorgensen CB, Bogelund M, Gundgaard J, Groleau D. The effect of hypoglycemia on health-related quality of life: Canadian results from a multinational time trade-off survey. Canadian journal of diabetes 38(1), 45-52 (2014).